

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appl. of: Naphtali Savion : Examiner: Zoreh Fay  
Serial No. 09/341,048 : Group Art Unit: 1618  
Filed: August 9, 1999  
For: PHARMACEUTICAL COMPOSITIONS FOR THE TREATMENT OF THE EYE

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

The undersigned, Michael Belkin, hereby declare and say the following.

1. I am a citizen of Israel, residing in Tel Aviv, Israel.

2. I am a Professor of Ophthalmology at the Tel Aviv University and the Director of Ophthalmic Technologies Laboratory at the University's Eye Research Institute at the Sheba Medical Center. I was awarded a Master's degree in Science by Cambridge University, in England, and a Medical Doctoral degree from the University of Jerusalem, in Israel.

3. I have previously served as Director of Research, Development and Non-Conventional Warfare Medicine in the Israel Defense Forces Medical Corps, Director of the Tel Aviv University Eye Research Institute and Chairman of the Tel Aviv University Department of Ophthalmology, and President of the Israel Society of Eye and Vision Research as well as one of the founders.

4. I am the author of over 200 scientific publications and of 15 patents. I am an internationally recognized eye researcher and have received various research awards. My laboratory is dedicated to enabling the transfer of technologies from the university-level research to clinical practice by providing expertise and facilities for the laboratory, pre-clinical and the clinical studies.

5. I am currently involved in several projects in lasers, optics, ophthalmic devices, pharmaceuticals and biotechnology, all of which are at various stages of development. I have been investigating the process of corneal healing for many years and, given that my laboratory is dedicated to the transfer of technologies from the laboratory to the clinic, I am well cognizant of both the research and the clinical practice on the subject.

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6. I am fully conversant with the medical conditions and pharmaceutical composition comprising a binder, including the subject of U.S. Patent Application Serial No. 10/048,789.

7. I wish to provide my professional opinion in support of the following statement made by others that a medicament for the treatment of disorders selected from the group consisting of: mechanical injury of the cornea; corneal epithelial defects created by spontaneous peeling of the epithelium; corneal defects following photo-refractive keratectomy; injuries caused by chemical damage to the corneal epithelium; conjunctiva; chronic edema of cornea with recurrent erosion of epithelium; and conditions following injury of epithelia due to radial keratotomy, i.e., the subject of the above-identified patent application, is useful in the treatment of dry eyes, whether by lubrication or inflammation suppression.

8. Furthermore, none of the therapies employed to cure the corneal conditions listed above is known to be associated with dry eyes treatment.

9. Consequently, a person skilled in the art would not consider using a dry eye medication to treat the disorders listed above, except occasionally for the temporary relief of some of their minor symptoms, for the treatment of the above conditions.

10. The undersigned Declarant declares further that all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; further these statements were made with the knowledge that willful false statements and the like so made are punishable by imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

dated 5, 2005

פרופ' מיכאל בלקין  
רופא עיניים  
מס' רישוי 8338-88

Michael Belkin, M.A., M.D.  
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